

REMARKS/ARGUMENTS

Claims 1-39 remain in this application. Claims 7-11, 21-25 and 34-36 have been withdrawn. Claims 1 and 15 have been amended. Review and reconsideration on the merits are requested in view of the foregoing amendments and the following discussion.

Claims 1-6, 12-20 and 26-28 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office objects to the use of the word "safe." This term is common in pharmaceutical applications and is accepted in the field. Furthermore, applicants have defined the term in paragraph [0039] of the application as published. Therefore, applicants submit that the term is not indefinite and request that the rejection be withdrawn with respect to this term.

Claims 15-20 stand rejected under 35 U.S.C. §112, first paragraph as being non-enabled for preventing hypocalcemia. Applicants have amended claim 15 to refer to treating these conditions as opposed to preventing them. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988) (citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986)). Applicants respectfully submit that the specification, when combined with information known in the art, satisfies the enablement requirement for claim 15 as amended. Therefore, applicants respectfully request that the rejection under §112 be withdrawn.

Claims 1-2, 15-17 and 26 stand rejected as being anticipated by U.S. Pat. No. 4,992,470 to Nissen. It is respectfully submitted that the Nissen document fails to disclose or suggest the present invention. Independent claims 1 and 15 of the present application recite treating elevated blood serum levels in a subject in need of such treatment and a subject having a condition associated with calcium and/or magnesium deficiency, respectively. Although applicants submit that these limitations were present in the claims as originally filed, these claims have been amended to clarify this distinction. These limitations are not disclosed or described in Nissen. It is axiomatic that all limitations must be considered in determining anticipation. Since these limitations are not present in Nissen there can be no anticipation. To the extent the Office is

taking the position that such disclosure is inherent, applicants respectfully disagree. Reliance on an inherent disclosure in a reference must be based on more than mere conjecture. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis in original) Accordingly, it is respectfully submitted that the Nissen document fails to disclose or suggest the invention claimed in the present application. Accordingly, it is respectfully requested that the rejection of these claims be withdrawn.

Claims 1-6, 12-20, 26-33 and 37-39 stand rejected as being unpatentable over Nissen in view of U.S. Patent No. 6,031,000 to Nissen et al. The Office action indicates that it would have been obvious to combine these references to arrive at the present invention. However, applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness because there is no suggestion in the prior art to combine these references as suggested by the Office and even when combined these references fail to disclose each limitation of the claims. Although a reference need not expressly teach that the disclosure contained therein should be combined with another or modified, the showing must nevertheless be "clear and particular." *Winner Royalty Corp. v Wang*, 202 F.3d 1340, 1348-1349 (Fed. Cir. 2002). Certainly, there is nothing recited in the cited references that provides "clear and particular" motivation to one of ordinary skill in the art to make the modifications as proposed in the Office action. Therefore, for at least this reason applicants submit that the claims are patentable over the cited references and request that the rejections be withdrawn.

Furthermore, with respect to claims 12-14, 26-28 and 37-39, which are directed to methods and compositions containing a combination of calcium and magnesium, the cited references fail to disclose or suggest such a combination. Furthermore, there is no motivation in the art or any of the cited references for modifying these teachings to arrive at the present invention. Therefore, for at least this reason as well applicants submit that these claims are patentable over the cited references and request that the rejections be withdrawn.

The claims also stand rejected based on double patenting over U.S. application 10/797946 and 10/658075. The '075 application has been abandoned thereby rendering this rejection moot. Applicants submit that claims directed to parenteral administration are not obvious over the claims of the '946 application which relate to oral administration.

In view of the foregoing, it is respectfully submitted that claims currently pending are distinguishable from the references cited and are in condition for allowance. Reconsideration of the rejections of record is respectfully requested. If the examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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